

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of:	Paul D. RUBIN et al.	Confirmation No.:	
Serial No.:	To Be Assigned Continuation of 09/985,099	Art Unit:	1615
Filed:	September 22, 2003	Examiner:	S. Tran
For:	METHODS FOR TREATING APNEA AND APNEA DISORDERS USING OPTICALLY PURE R(+) ONDANSETRON	Attorney Docket No:	4821-523-999

**INFORMATION DISCLOSURE STATEMENT**

**BOX PATENT APPLICATION**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of C.F.R. §1.56, there is hereby provided certain information for the Examiner's attention to be considered during the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record by executing the attached substitute Form PTO-1449 and returning it to the undersigned.

1. Enclosures accompanying this Information Disclosure Statement are:
  - 1a. ☒ Substitute Form PTO-1449.
  - 1b. ☐ Copies of references.
  - 1c. ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.
  - 1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.
2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b) before the latter of three months after the U.S. patent application

filing date or the first Office Action on the merits. Accordingly, no fee or certification is required.

3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the first Office Action on the merits, but before a Final Office Action or a Notice of Allowance.

*(Check either Item 3a or 3b)*

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$240.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed
  - ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 11-1650.

*(Item 3b to be checked if any reference known for more than 3 months)*

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after Final Office Action or Notice of Allowance, but before payment of Issue Fee.

A Petition to the Commissioner is hereby made under 37 C.F.R. §1.97(d) to request consideration of this Information Disclosure Statement. The \$130.00 fee set forth in 37 C.F.R. §1.17(i)(1) is:

- ☐ enclosed.
- ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 11-1650.

The Certification Statement in Item 5 below is applicable.

5. ☐ Certification Statement *(applicable if Item 3a or Item 4 is checked)*

*(Check either Item 5a or 5b)*

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ In accordance with 37 C.F.R. §1.97(e)(2), it is certified that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the undersigned after making reasonable inquiry, no item was known by any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

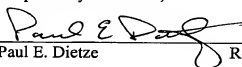
6. ☒ This is a continuation application under 37 C.F.R. §1.53(b) or (d).
- (Check appropriate Items 6a, 6b and/or 6c)*
- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.
- 6b. ☒ Copies of the publications listed on Form PTO-1449 from prior Application No. 09/985,099, filed November 1, 2001, which is a continuation of Application No. 09/515,407, filed February 29, 2000, have not been submitted pursuant to 37 C.F.R. §1.98(d). Copies will be provided if requested by the Examiner.
- 6c. ☐ Copies of the publications listed on Form PTO-1449 which were not previously cited in prior application Serial, filed on, of which this application claims priority under 35 U.S.C. §120, are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement. *(Check either Item 7a or 7b)*
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on, August 11, 1997.
- 7b. ☐ This Supplemental Information Disclosure Statement is timely filed within one (1) month of a PTO Notice under 37 C.F.R. §1.97(i).
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language reference is:
- ( Check Item 8a, 8b, or 8c)*
- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ satisfied because an English-language Abstract of each non-English-language reference is submitted herewith.
- 8d. ☐ enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Pennie & Edmonds LLP Deposit Account No. 11-1650.

10.

☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date: September 22, 2003

  
Paul E. Dietze

Reg. No. 45,627

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## LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY DOCKET NO.

4821-523-999

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APPLICANT

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FILING DATE

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GROUP

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## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	6,331,536	12/2001	Radulovacki et al.	514	214.02	
	A02	6,071,928	1/2000	Curtis et al.	514	278	
	A03	6,048,879	4/2000	Rubin et al.	514	327	
	A04	5,733,566	3/1998	Lewis	424	426	
	A05	5,712,302	1/1998	Young	514	397	
	A06	5,674,533	10/1997	Santus et al.	424	493	
	A07	5,639,476	6/1997	Oshlack et al.	424	468	
	A08	5,591,767	1/1997	Mohr et al.	514	413	
	A09	5,561,149	10/01/96	Azria et al.	514	397	
	A10	5,519,044	05/21/96	Imperato et al.	514	397	
	A11	5,502,067	3/1996	Morgan	514	397	
	A12	5,445,604	08/29/95	Lang	602	47	
	A13	5,422,374	6/1995	Miyao et al.	514	690	
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	A18	5,120,548	1/1992	McClelland et al.	424	473	
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	A20	5,075,290	12/1991	Findley et al.	514	46	
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	A26	4,835,173	05/30/89	Tyers	514	397	

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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A27	4,764,515	06/16/88	Borsa et al.	514	255	
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A31	4,008,719	2/1977	Theeuwes et al.	128	260	
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A36	3,536,809	10/1970	Applezweig	424	28	

**FOREIGN PATENT DOCUMENTS**

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
						YES NO
B01	WO 99/43319	09/02/1999	WIPO			
B02	WO 93 00075 A	01/07/93	WIPO			
B03	WO 91 07175 A	05/30/91	WIPO			
B04	WO 91 02524 A	03/07/91	WIPO			
B05	EP 0 411 900 A2	02/06/91	Europe			
B06	EP 0 201 165 A	11/12/86	Europe			
B07	EP 0 052 492	05/26/82	Europe			
B08	EP 0 100 569 A	02/15/84	Europe			
B09	GB 2 153 821 A	08/29/85	United Kingdom			

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C01	<u>Stedman's Medical Dictionary, 27<sup>th</sup> Edition</u>
C02	<u>Stedman's Medical Dictionary, 26<sup>th</sup> Edition, 1995, P. 114.</u>
C03	<u>Phillis, J. W., "Monoamines in the Central Nervous System," The Pharmacology of Synapses, 1970, Monograph, P. 43.</u>

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**OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)**

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C05	Naylor, R. J., et al., <i>Euro. J. Anaesth.</i> , 1976, vol. 9, Pp. 3-10.
C06	Desai, K. M., et al., <i>Br. J. Pharmacol.</i> , 1994, vol. 111, Pp. 346-350.
C07	Fozard, J. H., et al., <i>Br. J. Pharmacol.</i> , 1976, vol. 57, Pp. 115-125.
C08	Kim, M. Y., et al., <i>Heterocycles</i> , 1997, vol. 45(10), Pp. 2041-2043.
C09	Lochmuller, C. H., et al., <i>J. Chromatogr.</i> , 1975, vol. 113(3), Pp. 283-302.
C10	Ebert, W. R., <i>Pharm. Tech.</i> , 1977, vol. 1(5), Pp. 44-50.
C11	Burstein, E. S., et al., <i>J. Biol. Chem.</i> , 1995, vol. 270, Pp. 3141-3146.
C12	Messier, T. L., et al., <i>Pharmacol. Toxicol.</i> , 1995, vol. 76(5), Pp. 308-311.
C13	Bradley, P. B., et al., <i>Neuropharmacology</i> , 1986, vol. 25, Pp. 563-576.
C14	Dumuis, A., et al., <i>N. S. Arch. Pharmacol.</i> , 1989, vol. 340, Pp. 403-410.
C15	Miyata, K., et al., <i>J. Pharmacol. Exp. Ther.</i> , 1991, vol. 259, Pp. 815-819.
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C17	Berkow, R. et al. <i>The Merck Manual</i> , 1997, Pp. 154-155, 304-305, 1205-1206.
C18	Eliel, E. <i>Stereochemistry of Carbon Compounds</i> , 1962, Pp. xi-xv.
C19	Ariens, E.J., "Stereoselectivity in Pharmacodynamics and Pharmacokinetics," <i>Schweiz. Med. Wochenshr.</i> , vol. 120, no. 5, pages 131-134, February 3, 1990.
C20	Ariens, E.J., "Racemic Therapeutics - Ethical and Regulatory Aspects," <i>Eur. J. Clin. Pharmacol.</i> , vol. 41, no. 2, pages 89-93, 1991.
C21	Ariens, E.J., "Racemische Therapeutica Probleemmiddelen," <i>Pharmaceutisch Weekblad</i> , vol. 125, no. 2, pages 552-554, June 1, 1990 (Abstract).
C22	Butler, A. et al., "Pharmacological Properties of GR38032F, A Novel Antagonist at 5-HT <sub>3</sub> Receptors," <i>Br. J. Pharmacol.</i> , vol. 94, pages 397-412, June 1, 1990.
C23	Butler, A., "The Pharmacological Characterization of 5-HT <sub>3</sub> Receptors in Three Isolated Preparations Derived From Guinea-Pig Tissues," <i>Br. J. Pharmacol.</i> , vol. 101, pages 591-598, 1990.
C24	De Mulder, P.H.M. et al., "Ondansetron Compared with High-Dose Metoclopramide in Prophylaxis of Acute and Delayed Cisplatin-Induced Nausea and Vomiting," <i>Annals of Internal Medicine</i> , vol. 113, no. 11, pages 834-840, December 1, 1990. (Abstract)

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C25	Graves, T., "Chemotherapy-induced nausea and vomiting: Treatment options," Hosp. Formul., vol. 26, pages 474-476, 478-480, 485, 488, June 1991. (Abstract)
C26	Hibert, M.F. et al., "Conformation-Activity Relationship Study of 5-HT <sub>3</sub> Receptor Antagonists and a Definition of a Model for This Receptor Site," J. Med. Chem. vol. 33, no. 6, pages 1594-1600, 1990.
C27	Kusnierczyk, H. et al., "Antitumor Activity of Optical Isomers of Cyclophosphamide, Ifosfamide and Trofosfamide as Compared to Clinically Used Racemates," Journal of Immunopharmacology, vol. 8, no. 4, pages 455-480, 1986. (Abstract)
C28	Nukariya, N. et al., "Examination of anti-emetic effect, safety and usefulness of single oral dose of ondansetron tablet in nausea and emesis induced by anti-cancer drugs-dose-finding study of ondansetron tablet in patients receiving non-platinum anti-cancer drugs." Gan To Kagaku Ryoho, vol. 19, no. 9, pages 1347-1357, August 1992. (Abstract)
C29	Nukariya et al., "Examination of anti-emetic effect and safety of multiple intravenous doses of ondansetron in patients receiving nonplatinum anti-cancer drugs," Gan go Kagaku Ryoho, vol. 19, no. 9, pages 1375-1385, August 1992. (Abstract)
C30	Pinkerton, C.R. et al., "5-HT <sub>3</sub> antagonist ondansetron - an effective outpatient antiemetic in cancer treatment," Arch. Dis. Child., vol. 65, no. 8, pages 822-825, August 1990. (Abstract)
C31	Stevens, R.F., "The Role of Ondansetron in Paediatric Patients: A Review of Three Studies," Eur. J. Cancer, vol. 27, no. Suppl. 1, pages S20-S22, 1991. (Abstract)
C32	Testa, B. et al., "Racemates Versus Enantiomers in Drug Development: Dogmatism or Pragmatism?" Chirality, vol. 2, pages 129-133, 1990.
C33	Tonato, M., "Ondansetron Plus Dexamethasone: An Effective Combination in High-dose Cisplatin Therapy," Eur. J. Cancer, vol. 27, no. Suppl. 1, pages S12-S14, 1991. (Abstract)
C34	M. Radulovacki et al., <u>Serotonin 5-HT<sub>3</sub>-Receptor Antagonist GR 38023F Suppresses Sleep Apneas in Rats</u> , <u>Sleep</u> , vol. 21, no. 2, March 15, 1998, pages 131-136, Allen Press, Lawrence, KA..
C35	M. Yoshioka, et al., <u>Pharmacological Characterization of 5-Hydroxytryptamine-Induced Apnea in the Rat</u> , <u>I of Pharmacology and Experimental Therapeutics</u> , vol. 290, no. 2, 1992, pages 917-924.
C36	Y. Goda, et al., <u>The Role of 5-HT<sub>3</sub> Receptor Mediated Mechanisms on 5HT-3 Induced Apnea in Anesthetized Rats</u> , <u>European Journal of Pharmacology</u> , vol. 183, no. 3, 1990, pages 705-706.

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